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10/666,191

09/17/2003

Laszlo Prokai

UF-300XC2

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12/27/2006

SALIWANCHIK LLOYD & SALIWANCHIK
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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1617

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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3 MONTHS

12/27/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/666,191

Applicant(s)

PROKAI ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/04;8/04;3/05;10/05</u> . | 6) <input type="checkbox"/> Other: ____. |

First Office Action on the Merits

Priority

1. It is noted that this application appears to claim subject matter disclosed in prior Application No. 60/369,589, filed April 1, 2002. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is

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considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 8, 9, 13-16, 21-23 and 25 of copending Application No. 10/731,528. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass a method of providing estrogen compounds to a patient comprising the administration of a quinol. Unlike the instant invention, the copending Application is limited to treating ophthalmic disorders and in the scope of the claimed compounds. However, the compounds and the treatment method recited by the claims of the copending Application are obvious in view of the instant specification. For example, both claims encompass quinols that are converted to a biologically active compound in

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vivo (see for example, claim 13 of the present specification and claim 13 of the cited copending Application) and the present specification discloses utilization of the quinols in the treatment of diseases of the eye such as macular degeneration (see page 10, line 14-15 of the present specification).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

4. Applicant is advised that should claims 1, 14 and 20 be found allowable, claims 2-6 and 9; 18 and 19; and 24 and 25, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Note: The recitation of the method via which the quinol is converted or minimizing the undesirable side effect or the method via which it is regeneration is not limiting because the present specification does not make any differentiation between the claimed compounds.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claims recite the administration of **a quinol that is converted to a biologically active estrogen compound in vivo**. In essence, the instant claims encompass the utilization of any quinol that might be converted to a biologically active estrogen compound in vivo. However, (a) the present specification discloses "estrogen-related quinols" and set forth certain quinols that are useful as presently claimed and (b) the prior art lacks description of "estrogen-related quinols" or "a quinol that is converted

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to a biologically active estrogen compound in vivo". Therefore, in order to practice the claimed invention commensurate in scope with the instant claims the skilled artisan in the art would first have to test and obtain quinols that can be converted to biologically active estrogen compounds via enzymatic reduction as recited by the instant claims. The amount of experimentation necessary to make said determination would be undue because of the lack of correlation between a structure and "estrogen-related quinols" or "a quinol that is converted to a biologically active estrogen compound in vivo" in the present specification and the prior art.

Claims 10-12 recite the "treatment or prevention" of different conditions. The present specification however lacks guidance as to how the skilled artisan in the art would determine a patient in need of preventative treatment of the recited conditions. The present specification also lacks working examples as to the use of biologically active estrogen compounds in the prevention of the recited conditions. Therefore, in order to practice the claimed invention commensurate in scope with the instant claims, the skilled artisan would have to first search the literature for a model for the determination of said patient population. Because of the lack of guidance/working example or a model for said determination, the experimentation necessary to practice the claimed invention commensurate in scope with the instant claims would be undue.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-6, 8-12, 18, 19, 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

(a) Claims 1-6 and 8-12 recite the administration of a quinol that is converted to a biologically active estrogen compound in vivo with no identifying structure that correlates to said quinol. Therefore, the metes and bound of the claimed invention is indefinite.

(b) Claims 2-6, 9, 18, 19, 24 and 25 recite a method via which the quinol is converted or the undesirable side effect or the method via which it is regenerated. The present specification lacks differentiation between quinols having one or more of the recited characteristics and, thus, the skilled artisan in the art would be unable to determine the metes and bound of the claimed invention of each of the instant claims.

(c) Claims 10-12 recite diseases and/or conditions associated with menopause, bone or heart disease. It is unclear which diseases/conditions are encompassed by said limitations and, thus, the metes and bound of the claimed invention is unclear.

(d) Claim 19 is dependent on itself and, thus, is indefinite.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Jiu (US 2,910,486).

Jiu teaches 10-hydroxyestra-1,4-diene-3,17-dione and its estrogenic activity (see the entire article, especially col. 1, lines 15-33; Example 2 and claim 3). The method of use taught by the reference is encompassed by the instant claims.

11. Claims 14, 15 and 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Numazawa et al.

Numazawa et al. teaches 1,4-diene steroidal derivatives such as 2,4-dibromo-10 β -hydroxyl-1,4-estradiene-3,17-dione, 2,4-dibromo-10 β ,17 β -dihydroxyl-1,4-estradiene-3-one and 4-bromo-10 β ,17 β -dihydroxyl-1,4-estradiene-3-one and alcoholic solution thereof (see the entire article, especially pages 2059-2061, compounds 2a, 2c, 6a, 6b, 7a and 7c). The compounds and compositions taught by the reference are encompassed by the instant claims.

12. Claims 14, 20 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohe et al.

Ohe et al. teaches 10 β ,17 β -dihydroxy-1,4-estradiene-3-one and ethyl acetate solution thereof (see the entire article, especially page 111, Figure 1). The compound and composition taught by the reference are encompassed by the instant claims.

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13. Claims 14 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Jiu (US 2,950,291).

Jiu teaches 10-hydroxyl-1,4-estradiene-3,17-dione and 10,17-dihydroxyl-1,4-estradiene-3-one and their use in preparation of 17-oxygenated estra-1,3,5(10)-triene-1,4-diols and esters thereof (see the entire article, especially col. 1, lines 51-64; Examples 1 and 5a). The compounds taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiu (US 2,910,486).

Jiu teaches 10-hydroxyestra-1,4-diene-3,17-dione and its estrogenic activity (see the entire article, especially col. 1, lines 15-33; Example 2 and claim 3).

The instant claims differ from the reference by reciting the treatment of specific conditions/diseases. For example, claims 10-12 recite the utilization of the obtained biologically active estrogen compound in the treatment of conditions/diseases associated with menopause, bone and heart. However, the utilization of estrogens in

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the treatment of menopausal symptoms including osteoporosis, or as antioxidants is well known in the art (see "Background of the Invention" of the present specification). Thus, it would have been obvious to the skilled artisan in the art at the time of the present invention to utilize the estrogenic compounds taught by Jiu in the treatment of the conditions/diseases recited by the instant claims. The motivation would be based on the teachings of the estrogenic properties of the prior art compounds by Jiu and the knowledge in the art of the use of estrogens in treatment of the conditions recited by the instant claims.

It is noted that the skilled artisan would expect the compounds of Jiu to undergo biotransformation as recited by the instant claims because the prior art compounds are embraced by the claimed genus.

Note: Additional references showing the use of estrogenic agents in the treatment of conditions as recited by the instant claims will be provided upon request.


Telephone Inquiry

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
December 21, 2006